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CAE S			Application Number	09/379,851			
TRANSMITTAL			Filing Date	August 24, 1999			
FORM			First Named Inventor	Frank E. Joutras			
TRADEMACE (to be used for all correspondence after initial filing)			Group Art Unit	3764			
			Examiner Name	D. Pothier			
Total Number of Pages in This Submission 34			Attorney Docket Number	558-9-13-1			
		ENCL	OSURES (check	all that apply)			
Fee Transmittal Form X Fee Attached Amendment / Reply After Final Affidavits/declar Extension of Time Required Express Abandonment Information Disclosure Certified Copy of Priorit Document(s) Response to Missing P Incomplete Application Response to Mis under 37 CFR 1.	ration(s) uest Request Statement y arts/ sing Parts	Drawing Licensin Petition Petition Provisio Power of Change Address Termina Request CD, Nur	nent Papers Application) (s) g-related Papers to Convert to a mal Application of Attorney, Revocation of Correspondence I Disclaimer of for Refund mber of CD(s)	After Allowance Communication to Group Appeal Communication to Board of Appeals and Interferences X Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) Proprietary Information Status Letter Other Enclosure(s) (please identify below): self addressed, stamped postcard receipt			
	SIGNATURE OF	APPLIC	CANT, ATTORNEY, OR A	GENT S			
Firm or Individual name SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Vincent L. Carney, Attorney for the Applicant							
Signature Variant T. Carry							
Date July 2, 2002							
CERTIFICATE OF MAILING							
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EE TRANSMITTAL for FY 2002

Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT

(\$) 160.00

Complete if Known				
Application Number	09/379,851			
Filing Date	August 24, 1999			
First Named Inventor	Frank E. Joutras			
Examiner Name	D. Pothier			
Group Art Unit	3764			
Attorney Docket No.	558-9-13-1			

METHOD OF PAYMENT (check all that apply)	FEE CALCULATION (continued)					
X Check Credit card Money Other None	3. ADDITIONAL FEES					
Deposit Account:	Large Entity Small Entity					
Deposit Account 03-0778	Fee Fee Fee Fee Fee Description	Fee Paid				
Number	105 130 205 65 Surcharge - late filing fee or oath					
Deposit Account Name Vincent L. Carney	127 50 227 25 Surcharge - late provisional filing fee or cover sheet					
The Commissioner is authorized to: (check all that apply)	139 130 139 130 Non-English specification					
Charge fee(s) indicated below X Credit any overpayments	147 2,520 147 2,520 For filing a request for ex parte reexamina	tion				
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FEE CALCULATION	115 110 215 55 Extension for reply within first month					
1. BASIC FILING FEE Large Entity Small Entity	116 400 216 200 Extension for reply within second month					
Fee Fee Fee Fee Description	117 920 217 460 Extension for reply within third month					
Code (\$) Code (\$) Fee Paid	118 1,440 218 720 Extension for reply within fourth month					
101 740 201 370 Utility filing fee 106 330 206 165 Design filing fee	128 1,960 228 980 Extension for reply within fifth month	1				
107 510 207 255 Plant filing fee	119 320 219 160 Notice of Appeal					
108 740 208 370 Reissue filing fee	120 320 220 160 Filing a brief in support of an appeal	160				
114 160 214 80 Provisional filing fee	121 280 221 140 Request for oral hearing					
	138 1,510 138 1,510 Petition to institute a public use proceeding					
SUBTOTAL (1) (\$)	140 110 240 55 Petition to revive - unavoidable					
2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE	141 1,280 241 640 Petition to revive - unintentional					
Extra Claims below Fee Paid	142 1,280 242 640 Utility issue fee (or reissue) 143 460 243 230 Design issue fee					
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Claims -3	144 620 244 310 Plant issue fee					
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103 18 203 9 Claims in excess of 20						
102 84 202 42 Independent claims in excess of 3	146 740 246 370 Filing a submission after final rejection (37 CFR § 1.129(a))					
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and over original patent	169 900 169 900 Request for expedited examination					
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**or number previously paid, if greater, For Reissues, see above *Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$) 160.00						

SUBMITTED BY					Complete (if applicable)	
Name (Print/Type)	Vincent L. Carney	Registration No. (Attorney/Agent)	20,668	Telephone	402-465-8808	
Signature	Vereint 7. any			Date	July 2, 2002	

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3700 MAIL ROOM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF APPEALS

Patent Application

Applicant: Frank E. Joutras, et al. Group Art Unit: 3764

Serial No:

09/379,851

Appeal No:

Filed:

August 24, 1999

Examiner: D. Pothier

For

EXERCISE APPARATUS) Date: July 2, 2002

AND TECHNIQUE

BRIEF ON APPEAL

Commissioner for Patents Washington, D.C. 20231

Sir:

This brief is in support of the appeal filed by the applicant on May 13, 2002, from the final rejection of claims 1-12, made by the Examiner on January 2, 2002, in the above-identified application.

REAL PARTY IN INTEREST

The real party in interest is the assignee, Kinetecs, Inc., residing at 1000 West "O" Street, Suite 200, Lincoln, Nebraska 68528 as indicated by an assignment recorded with the U.S. Patent Office on microfilm reel 8176, frames 0805-0810.

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RELATED APPEAL AND INTERFERENCES

There are no other appeals or interferences known to applicant which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

The status of the claims now in this application is: (1) no claims are allowed; (2) claims 1-12 are rejected; (3) no claims are objected to; (4) claims 13-24 are withheld from examination; and (5) no claims are cancelled.

For convenience, claims 1-12 on appeal are retyped in appendix A.

STATUS OF AMENDMENTS

All amendments filed before final rejection are entered and there were no amendments filed after final rejection.

HISTORY OF THE APPLICATION

1. FILING

This application was filed on August 24, 1999, as a divisional of U.S. patent application 08/665,076 filed June 14, 1996, now U.S. Patent 5,954,621, which was a continuation-in-part of U.S. application 08/494,528 filed June 23, 1995, now U.S. Patent 5,980,435, which was a continuation-in-part of U.S. application 08/271,022 filed July 6, 1994, now U.S. Patent 5,976,063, which was a continuation-in-part of U.S. application 08/089,852 filed July 9, 1993, now U.S. Patent 5,788,618.

2. PROSECUTION

There were one information disclosure statement, two requirements for restrictions, one non-final Office action, one final Office action, one election of invention, two amendments, one petition to withdraw the requirement for restriction, and one appeal filed in this case.

SUMMARY OF INVENTION

This invention relates to an orthotic exercise device that provides controlled resistance to movement that is related in a pre-programmed manner to the position of the body part being exercised but is applied independently of speed (page 55, lines 8-11) so as to reduce pain and provide greater use of joints subject to arthrokinetic joint movement dysfunction. The resistance is programmed by an attending physician or physical therapist to provide resistance to the stronger opposing muscles in exertion or to the weaker muscles in support to permit the weaker muscles to function normally. The user may vary the speed along a resistance program which provides resistance to movement related to position but which does not generate an external force so unless the user is applying force, no resistance is applied by the equipment (page 55, lines 14-17).

In the preferred embodiment, means for controlling the amount of force includes one or more frictional resistance members that may include either: (1) a mechanism that releases for free movement in one direction and moves with resistance against force in the other direction; or (2) a mechanism that provides controlled variable or constant resistance in either or both directions (page 7, lines 7-16). In some embodiments, the friction members are level and flat disks while in others, the disks have contoured surfaces to

provide different amounts of friction at different locations in the movement of the device (page 9, lines 5-7 and page 58, lines 4-6). The orthotic exercise device 10 is part of or may be removably attached to a brace for a body part to control the amount of force needed to flex or extend the braced extremity or limb or other body part about a joint (page 7, lines 5-8).

Specifically, the exercise device 10 includes a standard limb brace portion 14, and first and second removable exercise modules 16A and 16B, one on each side of the limb brace portion.

The standard limb brace 14 (FIG. 1) includes a first support means 20, a second support means 22 and two pivotable joints 24A and 24B with the first support means 20 being fastened to a thigh or a forearm and the second support means 22 being fastened to a leg or an arm of a person. Each of the two sides of the first support means 20 is connected to a corresponding one of the two sides of the second support means 22 by a different one of the two pivotal joints 24A and 24B to be capable of limited movement under the control of the knee muscles or elbow muscles. (Page 19, line 20 through page 20, line 5; page 53, lines 13-19).

The control modules 16A and 16B (FIGS. 1, 2, 5 and 6) each include a control assembly 30A, a first lever assembly 32A and a second lever assembly 34A. The first and second lever assemblies 32A and 34A are fastened to the control assembly 30A on opposite sides thereof with the first lever assembly 32A being adapted to be fastened to the first support means 20 to move with the thigh or forearm of the person and the second lever assembly 34A being adapted to be fastened to the second support means 22 to

move with the leg or the arm of the person. (Page 20, lines 6-14 and page 53, lines 13-19).

The first and second lever assemblies 32A and 34A (FIGS. 1 and 2) each include a first affixed member 33A, a second snap-on member 35A, a first fastener 37A and a second fastener 39A. The affixed member 33A is permanently attached to a portion of the control module 30A and has an open portion adapted to receive a splint member of the lower support means 22 within a groove therein and the second snap-on portion 35A fits over the opposite side of the splint member with the fasteners 37A and 39A passing through both members to hold them together. (Page 20, lines 15-21).

In the preferred embodiment of control assembly (FIG. 42, control module 30H), the control assembly includes a bolt 74H, an inner lever 34H, a center friction disk 380H, an upper handle assembly 32H and an electronic program module 382H. The friction disk 380H is firmly attached to and electrically connects to the lower handle assembly 34H and rotates with respect to and is intermittently electrically connected to the upper handle assembly 32H to provide an electrical connection between the electrical programming section 382H and the friction assembly that includes the upper and lower handle assemblies and the friction disk 380H. With this arrangement, pressure between the handle assemblies and the friction disk is controlled by the program section 382H during flexion and extension (page 44, lines 6-15).

In one manner of providing friction, the lower handle assembly 34H includes a surface 385H that is magnetic and adapted to be pulled inwardly by a variable magnetic force. An outer conductive band 387 is adapted to cooperate selectively with electrical portions of the friction disk 380H and a plurality of openings 398H circumferentially spaced

from each other and underlying the friction disk 380H are in contact with conductors passing therethrough to form an electrical path interconnecting all of the conductors which pass normally through the disk 380H from top to bottom (page 44, line 21 through page 45, line 5 and page 58, lines 15 and 16).

In another manner of providing friction, a motor engages a bolt with is output shaft to drive the bolt in the manner of a ball screw and the lower plate or inner plate has cooperating threads in its central aperture that engage threads of the bolt in the manner of a ball screw and nut to move the two levers toward or away from each other as the motor rotates (page 45, lines 5-9 and page 58, lines 16-18).

The exercises device of this invention has several advantages, such as: (1) it can provide controlled resistance to movement in either direction; (2) it may be easily snapped onto existing braces to provide a controlled program of therapy without the need for expensive equipment; (3) it can provide a controlled and contoured resistance which depends on the position of the limb; (4) the controlled programs of resistance may be tailored to the individual and controlled by inserts into the exerciser; (5) the resistance is independent of the speed of motion; (6) there is no force applied by the equipment to a user in the absence of an attempt to move and the force is only a force of reaction; and (7) it can function as a component in virtual reality, muscle stimulation, biofeedback equipment and systems for reducing orthro-kinetic joint movement discord.

ISSUES

- 1. Whether claim 1 is anticipated by Whitelaw under 35 U.S.C. 102(b).
- 2. Whether claim 1 is obvious over Whitelaw under 35 U.S.C. 103(a).

- 3. Whether claim 1 is properly rejected under 35 U.S.C. 103(a) as being unpatentable over Airy in view of Whitelaw.
- 4. Whether claims 2-12 are properly rejected under 35 U.S.C. 103(a) as being unpatentable over Airy in view of Whitelaw and further in view of Stark.
- 5. Whether claims 1-2 and 12 are properly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent 5,788,618.
- 6. Whether claims 4, 10 and 11 are properly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent 5,788,618 in view of Whitelaw.
- 7. Whether claims 3, 5-6 and 8-9 are properly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent 5,788,618 in view of Stark.

GROUPING OF CLAIMS

The claims each recite different features and do not rise and fall together.

There is only one rational group of claims because claim 1 is the only independent claim with the other claims depending from it. However, claims 3, 5, 6 and 8 rise and fall together and claims 4 and 10 rise and fall together. Each of the claims is argued separately below.

REFERENCES RELIED UPON BY THE EXAMINER

The references relied upon in the final rejection consists of four U.S. patents, which are:

- (1) U.S. Patent 5,052,379 to Airy, et al.;
- (2) U.S. Patent 2,832,334 to Whitelaw;
- (3) U.S. Patent 5,052,375 to Stark, et al.; and
- (4) U.S. Patent 5,788,618 to Joutras.

DESCRIPTION OF THE REFERENCES

U.S. Patent 5,052,379 to Airy, et al.

U.S. Patent 5,052,379 to Airy, et al., discloses a combination brace and wearable exercise apparatus to selectively render a body joint immovable, control the movement of the body joint through a desired range of motion, and exercise the muscles associated with the body joint as the body joint is moved through a controlled range of motion and optionally monitor the movement of the body joint and exercise parameters electronically. The exercise module is attachable at a pivot joint assembly that interconnects the sections of the brace.

The friction module 36 (FIGS. 5 and 6) of Airy, et al. includes a cavity 236 containing a viscous fluid and rotor 232 and in one embodiment described in column 13, a further element that is a torsion spring is added. Resistance to movement is created by movement of the rotor in the cavity against the restraining force of the fluid in one embodiment and by a combination of a torsion spring and resistance of fluid in another embodiment. The spring force itself obviously varies with velocity in the manner of springs,

cannot be adjusted, is not a friction means and persists even after the applied force or motion stops. The friction module is described in columns 11-13 of Airy, et al.

Airy, et al., does not disclose a means for providing a predetermined resistance force nor a means for varying the resistance to movement of the first and second sections. Equipment is disclosed that could be modified for use in closed chain kinetic exercise if a different mechanism not speed dependent were provided for resistance to motion but not a controlled resistance independent of speed of motion. Airy, et al., teaches against such frictional resistances in the paragraph bridging columns 1 and 2 of the patent and does not teach the use of the apparatus or its modification for closed chain kinetic exercise.

U.S. Patent 2,832,334 to Whitelaw

U.S. Patent 2,832,334 to Whitelaw discloses a therapeutic device for use in the manipulative treatment of joints of the human body. The device comprises a pair of oppositely extending lever arms. One lever arm has a pair of L-shaped brackets slidably mounted thereon with a sling attached to the brackets while the other lever arm has U-shaped brackets slidably mounted thereon with hand grips on each of its legs. Whitelaw discloses a gear mechanism which applies force to the body to move it and which can be disconnected to allow the body to apply force to the device to test the strength of the muscles.

Whitelaw does not disclose an exercise device having a control device that varies the resistance over a cycle and can be fastened around a joint of the body.

U.S. Patent 5,052,375 to Stark, et al.

The patent to Stark, et al., relates to a personal orthopedic restraining device 2 for use to restrain flexibly connected body portions of an individual. The restraining device 2 includes an ambulatory housing 4, first and second distal end portions 4a and 4b, restraining means 6a and 6b for restraining movement of the first and second distal end portions 4a and 4b relative to one another, stress sensing means 8a and 8b for sensing stress on the restraining means 6a and 6b and control means 10 which includes a stress indicating means for indicating a quantitative stress value based upon an output from the stress sensing means, a recording means for recording the output from the stress sensing means and a microprocessor means for processing the outputs from the stress sensing means.

The stress sensing means 8a and 8b are attached to the restraining means 6a and 6b and the stress indicating means is interconnected with the stress sensing means for receiving an output from the stress sensing means.

In the preferred embodiments, the restraining means 6a and 6b can include an adjustable hinge 20a and 20b (FIGS. 3 and 4) interconnecting the distal end sections, wherein the angular position of the respective distal end section can be adjusted relative to one another. In some embodiments, the adjustable hinge may be an electromechanical hinge 21a and 21b (FIGS. 11 and 12). The adjustable hinge may be adjusted by the patient as directed by a physician or physical therapist so that a series of sets of isometric exercises can be conducted at different degrees of flexion or extension.

Stark, et al., does not disclose means for adjusting in a friction means wherein the friction means provides a preadjusted resistance to motion independent of the velocity of

the motion in a pattern to provide proper tracking nor does it suggest that arthrokinetic dysfunction can be cured by adjusting the resistance in the friction means to provide proper tracking.

U.S. Patent 5,788,618 to Joutras

No description of this patent is being submitted herein since this patent was cited solely for the basis of the rejection under the judicially created doctrine of obviousness-type double patenting.

THE REJECTIONS

35 U.S.C. 102(b)

The Examiner rejected claim 1 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Whitelaw on the grounds:

- (1) Whitelaw discloses an orthotic having a jointed limb brace having first and second sections and joint means, means for connecting the sections to the patient on opposite sides of a joint (see straps and brackets), friction means (see Fig. 4 and col. 2,1. 62-70) for varying resistance, the means being connected to the first and section sections adjacent the joint means and means for adjusting the resistance (see col. 2,1. 65-70) the friction means; and
- (2) if the means in Whitelaw are not viewed as anticipating applicants means, they are equivalent means since the strap and handle in Whitelaw function equivalently to connect sections of the orthotic to the patient on opposite

sides of the joint and to adjust the resistance by drawing two plates closer together.

35 U.S.C. 103(a)

- I. The Examiner rejected claim 1 under 35 U.S.C. 103(a) as being unpatentable over Airy in view of Whitelaw on the grounds:
 - (1) Airy discloses in Figures 1 and 5-12 and in column 2 lines 42-47 an orthotic used in rehabilitative therapy having a jointed limb brace having first and second sections, joint means, means for connecting the sections to the patient on opposite sides of a joint (see straps and sleeve), a resistance means (see Figs. 6, 8-9) for varying resistance, the means being connected to the first and section sections adjacent the joint means and means for adjusting the resistance (see col. 5,1, 1-7 1-7) the resistance means;
 - (2) however, Airy does not disclose that the resistance means is a friction means;
 - (3) Whitelaw teaches in Figure 4, in column 1, lines 35-39 and in column 2, lines 62-70 an alterative resistance mechanism used in rehabilitative orthotic which include a friction means to adjust the resistance during therapy to a limb;
 - thus, one skilled in the art would have known to use various resistance means on a rehabilitative orthotic for adjusting the resistance during therapy, including a friction means taught by Whitelaw;

- (5) if the means in Airy are not viewed as anticipating applicant's means, they are equivalent means since the strap and sleeves in Airy function equivalently to connect sections of the orthotic to the patient on opposite sides of the joint and to adjust the resistance of the device by reducing of space between two moving objects; and
- (6) in addition, Whitelaw teaches an equivalent means for adjusting resistance. See the above discussion.
- II. The Examiner rejected claims 2-12 under 35 U.S.C. 103(a) as being unpatentable over Airy in view of Whitelaw as applied to claim 1 above, and further in view of Stark on the grounds:
 - (1) As discussed above, Whitelaw teaches using two friction members in order to vary the resistance during use;
 - (2) in addition, Airy discloses in Figure 12 and in column 15, lines 1-62 that the means for adjusting includes a control unit (see Fig. 12 and col. 15) with a program and in column 15, lines 24-30 that feedback or a program can be provided to the user;
 - (3) however, Airy does not teach that the program controls the pressure between friction members;
 - (4) Stark teaches in column 21, lines 5-50 that it is known in the orthopedic rehabilitative art to program a control unit to control the resistance between

- two friction members in order to encourage the user to follow the exercise regiment of the physician (col. 21,1. 45-50);
- (5) thus, one skilled in the art would have known to include a program on the control unit of Airy that controls and adjusts the resistance between friction members in order to encourage the user to follow the exercise regiment of the physician;
- (6) as for claim 3, Stark teaches in column 21 that the friction members can be magnetically controlled in order to adjust resistance between the members;
- (7) as for claim 4, Whitelaw teaches that a screw is used to drive the friction members together and one skilled in the art would have known to use a motor to drive the screw in order to automate the device for ease of use;
- (8) as for claim 5, see Figure 1 of Airy;
- (9) as for claim 6, Airy discloses in column 4, lines 43-44 that the device is adapted to the elbow joint and as such, the first section is adapted to be connected to the forearm and the second section is adapted to be connected to the arm;
- (10) as for claim 7, Airy discloses in Figures 5-9 and in column 4, line 66 column5 line 5 that the resistance means is removably attached to the brace;
- (11) as for claims 8-11, Whitelaw teaches in Figure 4 that the friction members have both flat and curved surfaces and thus one skilled in the art would have known to make effective friction member both flat and curved; and
- (12) as for claim 12, see the above teaching of Stark and the program creates greater friction pressing the friction members together and are capable

pressing friction members together more tightly when the limbs are being moved in a direction aided by weakened muscles.

Obviousness-type Double Patenting

- I. The Examiner rejected claims 1-2 and 12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,788,618 on the grounds:
 - (1) although the conflicting claims are not identical, they are not patentably distinct from each other because claim 6 recites two sections and a controllable joint means for varying resistance which includes two friction members and a program controlling the pressure between the friction members; and
 - (2) as for claim 12, see the third paragraph of claim 6 and the fourth paragraph of claim 7.
- II. The Examiner rejected claims 4,10 and 11 under the judicially created doctrine of obviousness-type double patenting as beinig unpatentable over claims 1-7 of U.S. Patent No, 5,788,618 in view of Whitelaw on the grounds:
 - (1) Whitelaw teaches using friction disks with a screw mechanism on a rehabilitative orthotic in order to adjust resistance;
 - (2) however, Whitelaw does not disclose that the screw is motor-driven; and thus one skilled in the art would have known to include a motor to drive the screw in order to automate the device for ease of use; and

- (4) as for claims 10-11, Whitelaw teaches the friction members are both flat and curved and thus one skilled in the art would have known to make effective friction member both flat and curved.
- III. The Examiner rejected claims 3, 5-6 and 8-9 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,788,618 in view of Stark on the grounds:
 - (1) Stark teaches in column 21, lines 6-50 that it is known in the art to control resistance on a joint of an orthotic magnetically in order to control the movement between two friction members and thus, one skilled in the art would have known to use a magnet to drawn the friction members together in order to control movement between the friction members;
 - (2) as for claims 5 and 6, claims 1-7 of '618 do not disclose to what body part to connect the sections, except around a joint and thus, one skilled in the art would have known to connect the sections to many joint, such as the knee or elbow, and thus connect the sections to the thigh/leg and forearm/arm in order to rehabilitate the user; and
 - (3) as for claims 8-9, claims 1-7 of '618 disclose two solid surfaces but not whether they are flat or curved and absent a teaching as to criticality that friction members be curved or flat, this particular arrangement is deemed to have been known by those skilled in the art since the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement.

ARGUMENT

1. Summary

Claim 1 defines novel structure over the patent to Whitelaw in that the patent to Whitelaw does not disclose all of the claimed features of the claimed orthotic apparatus, namely Whitelaw does not disclose the first nor the last three paragraphs of claim 1.

The subject matter of claims 1-12 taken as a whole would have been unobvious to a person skilled in the art at the time of invention with the cited references before him because there is no teaching in the references of the unobvious problem solved by the claimed modifications. The modifications are themselves unobvious and in some respects, the references teach away from the novel structure. There is no motivation suggested in the references for combining them

Claims 1-6 and 8-12 are not properly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent 5,788,618 because claims 1-7 of U.S. Patent 5,788,618 do not recite any language corresponding to the first nor the last paragraphs inter alia of claim 1 in this application and claims 2-6 and 8-12 either directly or indirectly depend from claim 1.

2. <u>Issue 1</u>

Whether claim 1 is anticipated by Whitelaw under 35 U.S.C. 102(b)

For claim 1 to be anticipated by Whitelaw under 35 U.S.C. 102(b), Whitelaw must teach every aspect of the claimed invention which Whitelaw does not do. Whitelaw does not disclose:

"1. An orthotic apparatus for reducing arthrokinetic dysfunction after determining tracking problems after examining the patient comprising:

* * *

friction means for varying the resistance to movement of the first and second sections with respect to each other;

said friction means being connected to said first and second sections adjacent to said brace joint means; and

means for adjusting the resistance in the friction means wherein the friction means provides a preadjusted resistance to motion independent of the velocity of the motion in a pattern to provide proper tracking.".

Whitelaw in one embodiment teaches disconnecting the force that it normally uses to manipulate the limbs and permitting a constant friction to be applied to movement of the limbs by the patient. There is no teaching of the reduction of arthrokinetics dysfunction as defined in the specification on page 39 or determining a tracking problem or varying the resistance using the friction means nor a pattern to provide proper tracking. Instead, Whitelaw merely adjusts the frictional resistance to a constant preadjusted value as a typical exercise device. The specification clearly defines what is meant by the pattern, its purpose and effect and weight must be given to those recitations in the claims relating the these matters in a rejection under 35 U.S.C. 102.

3. <u>Issue 2</u>

Whether claim 1 is properly rejected under 35 U.S.C. 103 as obvious over Whitelaw.

Claim 1 recites a friction means for varying the resistance to movement of the first and second sections with respect to each other and a means for adjusting the resistance in the friction means whereby the friction means provides a preadjusted resistance to motion independent of the velocity of motion in a pattern to provide proper tracking. Whitelaw provides a nut which can adjust the resistance but once adjusted there is no mechanism for varying the resistance. There is no mechanism in Whitelaw for compensating with increased resistance to the stronger opposing or antagonistic muscles to permit the weaker muscles or agonistic muscles to function normally. It would not be obvious to attempt to make the nut disclosed in Whitelaw perform both functions or to incorporate some other mechanism to vary the resistance and to adjust the resistance without a teaching and that teaching is not provided by Whitelaw or by any other reference cited by the Examiner in this record. The failure to identify such a teaching that would lead to the modification that the Examiner may be suggesting is a failure to satisfy the Examiner's burden of establishing a prima facie case as to unpatentability under 35 U.S.C. 103 of claim 1 over Whitelaw.

The Examiner is correct that this clause like the other clauses in this claim, is controlled by paragraph 6 of 35 U.S.C. 112. Thus, it incorporates the language starting on page 39 of the specification relating to tracking. There is no mention of tracking nor any suggestion of it in Whitelaw.

Whitelaw does not suggest that pain is caused by improper tracking or that improper tracking is a problem to be cured by means of controlled resistance on each side of a joint.

The applicant has discovered that it is able to cure many painful arthrokinetic dysfunctions with the mechanism recited in claim 1 by properly aligning motion (tracking) of the muscular

motion. This method has proved surprisingly successful and applicant can submit under affidavit tests to show that result. The reduction of pain from patella-femoral problems has been reduced to the point so that patients who could not walk without crutches and could not climb stairs can when the apparatus as recited in claim 1 was applied after testing of the patients, as recited in claim 1.

Thus, claim 1 is not anticipated by Whitelaw under 35 U.S.C. 102(b) nor obvious over Whitelaw under 35 U.S.C. 103(a).

4. <u>Issue 3</u>

Whether claim 1 is properly rejected under 35 U.S.C. 103(a) as being unpatentable over Airy in view of Whitelaw.

Neither Airy, et al., nor Whitelaw are directed to the problem of tracking. Airy, et al., disclose an exercising device in which the force varies with velocity and which could not be used to selectively provide resistance to the antagonistic muscles to compensate for the weaker agonistic muscles so the agonistic and antagonistic can work together in a normal manner to prevent arthrokinetic dysfunction. Whitelaw discloses a fixed resistance but does not disclose varying that resistance as well as adjusting it to a preselected value.

Since neither of these references teach the overall purpose nor provide any reason why features of one should be incorporated in the other, it would not be obvious to incorporate the fixed resistance of Whitelaw into the resistance of Airy, et al. and to provide the mechanisms for providing a pattern of resistance that could avoid arthrokinetic dysfunction.

5. Issue 4

Whether claims 2-12 are properly rejected under 35 U.S.C. 103(a) as being unpatentable over Airy in view of Whitelaw and further in view of Stark.

Claims 2-12 define patentable subject matter over the patents to Airy, Whitelaw and Stark as follows:

Claim 2 depends from claim 1 and defines patentably over the combination of Airy, et al., and Whitelaw in the same manner as described above. Stark does not cure the deficiencies with respect to claim 1 because it does not teach a program related to varying and adjusting the resistance independently of the velocity to provide proper tracking.

Claim 2 in addition to containing the same recitations as claim 1 also recites that the means for adjusting includes a control means having a program, said program controlling pressure between the first and second friction members. Stark has a program which is intended to monitor the exercises being performed by the patient to avoid improper exercise. Thus when the patient has performed a required number of repetitions, Stark would apply pressure to the exercise unit to stop the patient from proceeding further. As the Examiner argues, Stark says this is to encourage the patient to follow the routine and that's true but the Examiner is mistaken in alleging that this teaching is a reason why someone would incorporate the invention of Stark with the teachings in Whitelaw and Airy, et al.

Claim 2 recites that the means for adjusting the pressure includes the program means whereas the program means taught by Stark is an overall program means that even wakes the patient up and reminds the patient that it is time to start exercising. It is not part

of the means for applying pressure. No one with Stark, Whitelaw and Airy, et al., would find it obvious to combine the teachings of these very diverse patents to obtain the invention covered by the claims of this application.

The Examiner is constructing the claimed invention from hindsight by pulling parts of other systems together to accomplish the purpose taught in this application. Stark does not provide any guidance that would cause a person of ordinary skill in the art to make the combination that would meet claim 2 but would create an entirely different combination which would ensure that the patient follows a program that he has a volition to change. Claim 2 is directed to a program that controls resistance to movement for the purpose of correcting the tracking of the muscles.

Claim 3 depends form claim 2 and is patentable for the same reasons as claim 2. However, it also recites that the pressure between the first and second friction members is controlled magnetically. The Examiner states that this is taught by Stark but it is not taught by Stark. Stark teaches stopping the exercise magnetically whereas claim 3 recites the friction members that are programmed to control resistance to movement for the purpose of correcting for false tracking is controlled magnetically. There is no teaching of this in any of the references cited by the Examiner. The subject matter of the claim must be considered as a whole and when considered as a whole, the control of the friction disks magnetically relates to tracking not to controlling the patient so that the patient obeys the physician's orders.

Claim 4 depends from claim 2 and is patentable for the same reasons but it also recites that the pressure between the first and second friction members is controlled by a motor-driven screw drive means. The Examiner states that this would be obvious because

Whitelaw discloses a finger tightened screw to adjust the fixed resistance of the friction members. The Examiner then states, with no explanation, that it would be obvious to automate that process. The problem is that automating that process would still not provide a variation in the resistance in accordance with a program and it is not clear how someone automates a finger adjustment of a screw to set the pressure or just what that automation would accomplish. Thus, the motor driven screw for adjusting the two friction members, when the claim is considered as a whole, is an additional reason why claim 4 is patentable over the cited references.

Claim 5 depends from claim 3 and is patentable for the same reasons. However, it also recites that the first section is sized and constructed to one of a leg and thigh and the second section is sized and constructed to be connected to the other of a leg and thigh. It is patentable for the same reasons as claim 3.

Claim 6 depends from claim 3 and is patentable for the same reasons a claim 3.

Claim 7 depends from claim 3 and is patentable for the same reasons. Moreover, it recites that the friction means is removably attached to said first and second sections over said brace joint means. This permits easy changing of the program as a patient progresses and the arthrokinetic dysfunction changes with time. There is no reason provided in the cited references for such a feature nor are the cited references designed to permit such an activity. Accordingly, claim 7 is patentable for this additional reason.

Claim 8 depends from claim 3 and is patentable for the same reason.

Claim 9 depends from claim 3 and is patentable for the same reason. Moreover, it recites that the first and second friction members are curved surfaces. The curved surfaces permit three dimensional control of a joint, which is not taught by the cited

references. The applicant can find no teaching in Whitelaw of first and second curved frictional members. There appears to be only one pair of frictional disclosed in the combination of Whitelaw, the ones tightened by a screw.

Claim 10 depends from claim 4 and is patentable for the same reasons.

Claim 11 depends from claim 4 and is patentable for the same reasons. Moreover, it recites that the friction members are curved members and the references do not teach curved members. The curved members permit three dimensional control about a joint. There is no teaching of this accomplishment in the prior art and claim 11 is patentable for this additional reason.

Claim 12 depends from claim 2 and is patentable for the same reasons. Moreover, it recites that the program creates greater friction by pressing the friction members together tightly when the limbs are moved in a direction aided by weak muscles to provide greater support for weak muscles. The applicant has found by clinical studies that people with patellofemoral injuries, for example, can be enabled to walk and climb steps and the like which they could not do before through the use of the apparatus covered in claim 12. There is no teaching in the prior art of anything else that accomplishes this purpose much less anything having the features covered by claim 12.

None of these references disclose the last paragraph of claim 1 as interpreted under 35 U.S.C. 112, paragraph 6, and no combination of them can provide such a disclosure. Moreover, none of them provide the suggestion that arthrokinetic dysfunction can be cured by adjusting the resistance in the mechanism as disclosed in claim 1 to provide proper tracking. This concept is unobvious and results in the solution as recited in claim 1 being unobvious to a person of ordinary skill in the art at the time of the invention.

The subject matter of the claims taken as a whole would have been unobvious to a person skilled in the art. There is no overall suggestion in the references that would cause a person of ordinary skill in the art to incorporate teachings from one reference to another reference to create a combination upon which the claims can be read. When a combination of references is necessary, the combination must fairly suggest the invention and thus must suggest the teachings be combined. There must be a rationale or logic that would cause a person of ordinary skill in the art to make such a combination and there is no sound logic showing that a person of ordinary skill in the art would modify any of them in view of the other or in view of known knowledge to arrive at the claimed invention.

The United States Patent and Trademark Office has the burden of showing this logic and that burden has not been satisfied.

6. <u>Issue 5</u>

Whether claims 1-2 and 12 are properly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent 5,788,618.

Claims 1-7 of the former patent to Joutras are all missing the teaching in the last paragraph of claim 1 and the teaching of claim 12 of this application. None of these claims relate to providing tracking by compensating for the weakened muscles to permit normal tracking. Even in a double patenting rejection, the claims must be interpreted as a whole and when a claim 1, 2 and 12 are interpreted as a whole, they are inventive over claims 1-7 of the former patent to Joutras. It is unobvious over claims 1-7 of Joutras to compensate for tracking and particularly with the detail recited in claim 12.

7. <u>Issue 6</u>

Whether claims 4, 10 and 11 are properly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent 5,788,618 in view of Whitelaw.

Claims 4, 10 and 11 all depend directly or indirectly from claim 1 and avoid double patenting over claims 1-7 of the former Joutras patent for the same reasons. The patent to Whitelaw does not render the tracking concept obvious. Similarly, Whitelaw does not disclose a motor driven screw nor make it obvious over the claims 1-7.

8. Issue 7

Whether claims 3, 5-6 and 8-9 are properly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent 5,788,618 in view of Stark.

Claims 3, 5-6 and 8-9 all depend directly and indirectly from claim 1 and avoid double patenting over claims 1-7 of Joutras for the same reasons that claim 1 avoids double patenting. The addition of the teachings of the patent to Stark does not change this situation because the patent to Stark does not make the adjustment of resistance for curing tracking problems obvious. Similarly, Stark does not teach the programming of the resistance members as claimed in claim 2 nor the magnetic control of those features as covered by claim 3 that depends from claim 2 nor those features as incorporated in claims 5 and 6 which depend from claim 3 nor those features in claims 8 and 9 that also depend from claim 3.

9. CONCLUSION

There is a common reason why the rejections of the Examiner in this application are

erroneous and should be reversed. The Examiner has started with the concept in this

patent application and reconstructed the claimed invention by taking parts from other

applications relying on hindsight. The overall combination covered by the claims is not

taught by any of the cited references nor are the claims the same invention as claims 1-7

of the patent to Joutras nor is it obvious over claims 1-7 of the patent to Joutras in view of

the patent to Whitelaw or the patent to Stark.

Accordingly, it is respectfully requested that the final rejection of the Examiner be

reversed.

Respectfully submitted,

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APPENDIX A

Claims on Appeal as of July 2, 2002

Claims 1-12:

1. An orthotic apparatus for reducing arthrokinetic dysfunction after determining tracking problems after examining the patient comprising:

a jointed limb brace having a first section, a second section, and a brace joint means;

means for connecting said first section and second section to the patient whereby the first section may be connected to a portion of a limb of a person on one side of a joint of the limb and the second section to a portion of a limb of a person on the opposite side of the joint of the limb;

friction means for varying the resistance to movement of the first and second sections with respect to each other;

said friction means being connected to said first and second sections adjacent to said brace joint means; and

means for adjusting the resistance in the friction means wherein the friction means provides a preadjusted resistance to motion independent of the velocity of the motion in a pattern to provide proper tracking.

2. Orthotic apparatus according to claim 1 in which said friction means includes first and second friction members and the means for adjusting includes control means having

a program; said program controlling pressure between said first and second friction members.

- 3. Orthotic apparatus according to claim 2 in which the pressure between said first and second friction members is controlled magnetically.
- 4. Orthotic apparatus according to claim 2 in which the pressure between said first and second friction members is controlled by a motor-driven screw drive means.
- 5. Orthotic apparatus according to claim 3 wherein the first section is sized and constructed to be connected to one of a leg and thigh and the second section is sized and constructed to be connected to the other of a leg and thigh.
- 6. Orthotic apparatus according to claim 3 wherein the first section is sized and constructed to be connected to one of a forearm and arm and the second section is sized and constructed to be connected to the other of a forearm and arm.
- 7. Orthotic apparatus according to claim 3 in which said friction means is removeably attached to said first and second sections over said brace joint means.
- 8. Orthotic apparatus in accordance with claim 3 in which the first and second friction members are flat surfaces.

- 9. Orthotic apparatus in accordance with claim 3 in which the first and second friction members are curved surfaces.
- 10. Orthotic apparatus in accordance with claim 4 in which the first and second friction members are flat surfaces.
- 11. Orthotic apparatus in accordance with claim 4 in which the first and second friction members are curved members.
- 12. Orthotic apparatus in accordance with claim 2 in which said program creates greater friction by pressing the friction members together more tightly when the limbs are being moved in a direction aided by weakened muscles, whereby weakened muscles are given greater support than stronger muscles.